# California Health and Human Services Agency (CHHS)

# California Department of Public Health (CDPH)

# COVID 19 VACCINE SCIENTIFIC SAFETY REVIEW WORKGROUP

## October 29, 2020 - 4:00pm – 5:30pm

# MEETING SUMMARY

**Workgroup Members Attending**

**Tomas Aragon, MD**, Health Officer, City & County of San Francisco; **Eric Goosby, MD**, Distinguished Professor of Medicine and Director of the Center for Global Health Delivery, University of California, San Francisco; **Rodney Hood, MD**, Trustee, Alliance Healthcare Foundation; **Nicola Klein, MD**, Director, Kaiser Permanente Vaccine Study Center; **Grace Lee, MD**, Professor of Pediatrics and Associate Chief Medical Officer for Practice Innovation, Stanford Children's Health; **Bonnie Maldonado, MD**, Professor and Chief of the Division of Infectious Diseases, Department of Pediatrics, Stanford Medicine; **Arthur Reingold, MD**, School of Public Health Division Head of Epidemiology and Biostatistics, University of California, Berkeley; **Mark Sawyer, MD**, Infectious Disease Specialist, Rady Children's Hospital; **Rob Schechter, MD**, Chief, California Department of Public Health, Immunization Branch; **Peter Szilagyi, MD**, Professor and Vice Chair for Clinical Research, Department of Pediatrics and Mattel Children's Hospital; **Matt Zahn, MD,** Medical Director, Communicable Disease Control Division, Orange County Health Care Agency

**California State Representatives Attending**

**Mark Ghaly, MD**, Secretary, CA Health and Human Services Agency; **Erica Pan, MD**, Interim State Health Officer; **Richard Figueroa**, Deputy Cabinet Secretary for Health, Office of the Governor, California; **Tricia Blocher**, Deputy Director, Office of Emergency Preparedness, California Department of Public Health **Ron Chapman**, MD, MPH, Former Director, California Department of Public Health.

**Western States Representatives Attending**

STATE OF WASHINGTON:

**Kathy Lofy, MD**, State Health Officer and the Chief Science Officer for Washington State
**Molly Voris**, Special Advisor for Pandemic Health Response to Governor of Washington
**Michele Roberts**, Department of Health Prevention and Community Health Assistant Secretary

STATE OF NEVADA:

**Richard Whitley**, Secretary, Nevada Department of Health and Human Services
**Candice McDaniel**, Health Bureau Chief, Bureau of Child, Family, and Community Wellness
**Ihsan Azzam, MD**, Chief Medical Officer, Division of Public and Behavioral Health

STATE OF OREGON
**Laura Byerly, MD**, Chief Medical Officer, Virginia Garcia Health Center
**Rex Larsen**, Quality Improvement Program, Oregon Health Authority
**Linda Roman**, Health Policy Advisor to Governor of Oregon

**Consultants:**
**Bobbie Wunsch**, Founder and Partner, Pacific Health Consulting Group
**Laura Hogan**, Senior Health Consultant, Pacific Health Consulting Group

**Welcome, Purpose of the Workgroup, Review Agenda and Introductions**

*Mark Ghaly, MD, MPH, Secretary, California Health and Human Services Agency (CHHS)*
*Erica Pan, MD, MPH, Interim State Health Officer*
*Arthur Reingold, MD, Chair*

Secretary Ghaly welcomed everyone on behalf of the Governor. This group of California experts and leaders was joined by representatives from three additional Western States, Washington, Oregon, and Nevada to prepare for COVID vaccines being available. This is unlike any other time, where even before the vaccine is available, there is so much conversation, commotion, and confusion. We appreciate being able to work with you as clinical and medical research leaders from California, and now welcoming Washington, Oregon, and Nevada, to assess and signal the safety of the vaccine and that no corners were cut. Having this group of world-class experts provide guidance and recommendations will go a long way to support and reassure Californians to be vaccinated. The Governor and I believe the work of this group will be additive to other efforts and is a necessary part of looking closely at the opportunities and challenges for California. I want to thank each of you for agreeing to be available for this.

Dr. Pan welcomed the group. We are fortunate and honored to have such diverse and deep expertise in immunizations, vaccine trials and public health. Many of you are current or former working group members of the Centers for Disease Control (CDC) Advisory Committee on Immunization Practices (ACIP). This group is not to replace, but to validate the process of assessing vaccine safety and reassure the public whether the normal process and checks and balances were followed before approval for distribution, and advise the State of California about the different approved vaccine(s).

Dr. Reingold introduced himself as the chair of the workgroup. He welcomed the group and added his appreciation for those on the front lines of public health. This effort is important, and we are privileged to have members of ACIP in the workgroup. From the outset, we want to emphasize that this workgroup is not to supplant federal efforts, the Federal Drug Administration (FDA), Vaccine and Related Biological Products Advisory Committee (VRPAC) and ACIP, but to do everything we can to make sure that people in our States feel comfortable and reassured and are willing to sign on for safe and effective vaccine(s) once they become available.

Each member of the workgroup and state agencies as well as representatives from other states introduced themselves and offered information about their respective backgrounds.

**Introduction of Western States, Structure, Governance and Timeline for Workgroup**
*Erica Pan, MD, MPH, Interim State Health Officer*
*Tricia Blocher, Deputy Director, Office of Emergency Preparedness, CDPH*
*Arthur Reingold, MD, Chair*

Dr. Pan offered overview comments about the structure and role of the workgroup. The role of the Scientific Safety Review Workgroup is to review the available data and provide independent recommendations to us in California and our partner states to inform vaccine planning and implementation efforts and to reassure the public about our confidence in the process for federal approval and safety of the vaccine(s). There is also a Drafting Guidelines Workgroup that will focus on California specific guidance for prioritization and equitable allocation of COVID vaccine(s). This is a multidisciplinary group with physicians and physician scientists, public health practitioners, pharmacists, and an ethicist, among others. This group will base its work on national and federal guidance, and will look at the specifics for the state, such as how many health care workers do we have, how are we categorizing them and how are we allocating vaccine with equity in mind. The Community Advisory Committee is a larger group representative of a diversity of stakeholder groups that will offer input and feedback on the planning efforts. This group will also help work through the barriers to implementation and consider equity in its discussions, and we hope will help us get communications and messages to our important stakeholder partners.

This Scientific Safety Review Workgroup will inform Secretary Ghaly and the California Department of Public Health (CDPH) of its assessment of COVID-19 vaccine safety as they advise the Governor. Dr. Reingold will chair this group. In addition, as mentioned previously, many of you have appointments on federal committees, such as the Vaccine and Related Biological Products Advisory Committee (VRBPAC), an ad hoc committee of the National Academies of Sciences, Engineering, and Medicine that developed an overarching framework for SARS CoV-2 (COVID-19) vaccine allocation, and ACIP. We hope that will facilitate timely access to the relevant data and information and coordination across all of these efforts.

We do not plan to have a formal governance structure or voting. We are looking for an overall assessment of the information and for the workgroup to develop a position statement of its assessment of the safety of each COVID-19 vaccine approved for use in the United States.

As with many aspects of the COVID 19 pandemic, things evolve rapidly, and we expect to continue to clarify issues and timelines as we move forward. We plan to have 1-2 additional meetings to establish a process and prepare for FDA approval of candidate COVID-19 vaccine(s). We are asking you to be available as information concerning COVID-19 vaccine(s) is shared by

manufacturers. We plan to convene the workgroup within 24 hours after FDA approvals to discuss your assessment of safety and your recommendations.

There will be summaries of each meeting. We look forward to discussions with you about how we will work together effectively and share information with the public. Responses to media inquiries about your role in this workgroup should be coordinated through Suanne Buggy (suanne.buggy@cdph.ca.gov), our communications liaison. We will provide talking points about your role and the role of the workgroup. An important part of public trust is having consistent messages and our goal is to avoid any confusion for the public. We will follow up with each member to document any declarations of potential conflicts of interest.

We are excited to have a multi-state collaboration and the input and perspectives of our Western States Partners. Our partners from other states will use information and findings separately as planning proceeds for each state.

**Member Comments and Discussion**

Media inquiry process

- In terms of the media communication, some of us do press conferences on a regular basis. I would ask that talking points are updated as we move along so that if a need arises, we can use them.

- CDPH requested that workgroup members refer reporters and inquiries to Suanne Buggy to streamline communications and ensure consistent messaging important to building public trust and avoiding public confusion.

Timeframe for recommendations

- I see this collaboration as important for supporting our state and other states with regard to decision making and implementation. With that spirit in mind, I am not worried about data coming through. I also appreciate the cross-state border collaboration to avoid confusion for border communities. The more aligned with contiguous states we can be, the better for communities. In addition, I hope there is common ground across all 50 state implementation plans so people are not confused.

Duration of the work group

- The current scope of work focuses on what happens up until the point of licensure. There are likely to be multiple vaccines that will be licensed over the next three to nine to nine months. Will there be a post-approval phase or are we going to only look at the pre-approval phase data? Is there an opportunity for this group to bridge the gap between recommendation and implementation and communication?

- There may be three or four vaccines in the next several months and there could be another vaccine 12-18 months later. It may be too much to hope that the need for additional trust will have declined by then, so we need to think about what the role of this workgroup would be over time. In addition, we will learn more over time about safety as larger numbers of people get these vaccines and we need to consider whether there is a role for this group as safety data come out post licensure.

- CDPH responded that the main role is pre-approval and assessment as new vaccines are approved, which may be over a period of months. We are not able to determine a regular calendar for meetings and that has led us to ask for you to be on-call to convene quickly as new vaccines are approved. We will do as much prep as possible ahead of time. The other role is to provide input to implementation and allocation guidelines. There will be a natural overlap with the other workgroup and there may be clinical questions that this group can inform.

Operation Warp Speed overview

- CDPH let members know there is a link to the plan provided in the FAQs, and we are drafting a three-page summary to send to you. The link we previously sent you is the full 80 page report. At the next meeting, we can do an overview of that plan.

Balancing transparency and efficiency.

- Transparency is incredibly important from a trust perspective and I really appreciate that community engagement is built in. In addition, as much as is appropriate, I would favor transparency around vaccine safety as a critical component of monitoring.

- Public meeting rules vary significantly across states. Given we have multiple States participating, we might have additional considerations on the public rules.

- ACIP has both closed and public meetings. The National Academy of Science, Engineering and Medicine (NASEM) has a different approach altogether. I understand this is an important issue because the intent is to be transparent.

- One issue is that ACIP and other organizations' public meetings are very formal. In a more informal group, it could be hard to have discussion without being misinterpreted by the public. The concept of having workgroup sessions that are not public meetings as well as formal meetings is appealing to me.

Selecting from multiple vaccines

- CDPH commented that, especially in the beginning, vaccines are likely to be scarce. If we deem them safe and there are no concerns, we would use one or more vaccines. This group is really about is it safe; what are the efficacy data? There may be decisions about which vaccine we should allocate or distribute to specific populations. If we have multiple vaccines, there may be operational decisions that need to be made and this group could help with such decisions.

Reviewing efficacy data

- There may be different levels of evidence for efficacy in different subgroups. For example, there may be more or less evidence in those over 65 or in some trials versus others. My question is efficacy, are we going to get to the point where there are multiple vaccines and there is more or less evidence potentially, for doses of COVID-19 different populations.

- Safety is the balance of efficacy and harm and it could become important later on. California has an asset in the Vaccine Safety Datalink (VSD) system. I am wondering how much of this committee can focus on communication about how we monitor vaccine safety. What are we doing in real time? Highlighting the VSD system that exists in California will be helpful to reassure people.

- I understand our mission is not to evaluate efficacy, but a goal would be to use the most effective and the safest vaccine and provide recommendations on how to implement that in the most ideal way.

- CDPH commented that the initial intent is definitely to focus on safety. This is a good dialogue to keep discussing with this brain trust. This committee can be the trusted science group. We will also work with the Community Advisory group and communications staff to get the word out.

Resources to consider

- If healthcare personnel are vaccinated first, the other system to think about using is the National Healthcare Safety Network. The module for COVID vaccine administration and safety is not yet up, but it may be available soon. The other is the Be Safe module, which is still under development. It might be an important arm of monitoring safety for California. It could also be important for the country because the population in the Western States is large. If we can do this in a coordinated way, it gives us an opportunity to actually have early eyes on safety.

**Overview of Vaccine Approval Process**

*Robert Schechter, MD, MPH, Chief, Immunizations Branch, CDPH*

Dr. Schechter presented an overview of the Food and Drug Administration (FDA) process and timeline. The dates for approval of vaccine(s) are uncertain. FDA guidance on safety and efficacy outcomes for current phase II clinical trials and discussion from the October 22, 2020 Vaccine and Related Biological Products Advisory Committee (VRBPAC) meeting were reviewed. Vaccine trial data will be submitted to the FDA and advisory committees for review. Should FDA authorize use of a vaccine, the federal Advisory Committee on Immunization Practices (ACIP) would convene shortly thereafter to discuss recommendations for use.

**Member Comments and Discussion**

Timing of ACIP and this workgroup

- ACIP will convene an emergency meeting once there is FDA approval. It will be important to prepare as much as possible in advance to have as much time as possible with the data. The ACIP emergency meeting will be an open meeting but it is hard to predict if the data will be sufficient to come to a conclusion.

- There are some that want an ACIP meeting within 24 hours after FDA approval, but that may not happen if there is not enough time to put together the data to have a meaningful conversation and a potential recommendation.

**Closing Comments and Adjourn**

*Arthur Reingold, MD, Chair and Erica Pan, MD, MPH, Interim State Health Officer*

Dr. Pan closed the meeting with her appreciation to the group for the time and to the depth of conversation in this first meeting.